

**STATE OF MISSOURI
MISSOURI BOARD OF PHARMACY**

IN RE:)	
)	
DOUGLAS C. KLEIN, R.PH.)	
License No. 044202)	Complaint No. 2016-005583
829 SW Stablewood Court)	
Lee's Summit, MO 64081)	

**SETTLEMENT AGREEMENT BETWEEN THE
MISSOURI BOARD OF PHARMACY AND DOUGLAS C. KLEIN**

Come now Douglas C. Klein, R. Ph. ("Respondent" or "Licensee") and the Missouri Board of Pharmacy ("Board" or "Petitioner") and enter into this Settlement Agreement for the purpose of resolving the question of whether Respondent's license to practice pharmacy will be subject to discipline.

Pursuant to the terms of Section 536.060, RSMo, the parties hereto waive the right to a hearing by the Administrative Hearing Commission of the State of Missouri and, additionally, the right to a disciplinary hearing before the Board under Section 621.110, RSMo, and stipulate and agree that a final disposition of this matter may be effectuated as described below.

Respondent acknowledges that he understands the various rights and privileges afforded him by law, including the right to a hearing of the charges against him; the right to appear and be represented by counsel; the right to have all charges against him proven upon the record by competent and substantial evidence; the right to cross-examine any witnesses appearing at the hearing against him; the right to a decision upon the record by a fair and impartial administrative hearing commissioner concerning the charges pending against him and, subsequently, the right to a disciplinary hearing before the Board at which time he may present evidence in mitigation of discipline; and the right to recover attorney's fees incurred in defending this action against his license. Being aware of these rights provided him by operation of law, Respondent knowingly

and voluntarily waives each and every one of these rights and freely enters into this Settlement Agreement and agrees to abide by the terms of this document as they pertain to him.

Respondent acknowledges that he has received a copy of the draft Complaint to be filed with the Administrative Hearing Commission, the investigative report, and other documents relied upon by the Board in determining there was cause for discipline against Respondent's license.

For the purpose of settling this dispute, Respondent stipulates that the factual allegations contained in this Settlement Agreement are true and stipulates with the Board that Respondent's license to practice pharmacy, numbered 044202, is subject to disciplinary action by the Board in accordance with the provisions of Chapter 621 and Chapter 338, RSMo.

JOINT STIPULATION OF FACTS

1. The Board is an agency of the State of Missouri created and established pursuant to Section 338.140, RSMo¹, for the purpose of executing and enforcing the provisions of Chapter 338, RSMo.

2. Respondent Douglas C. Klein is licensed as a pharmacist under the laws of the State of Missouri, License No. 044202. Respondent's license was at all times relevant herein current and active.

3. At all relevant times herein, Respondent was employed as Pharmacist-in-Charge ("PIC") at Heart of America Pharmacy, LLC, 4338 E. 142 St., Grandview, MO 64030 (the "Pharmacy").

4. Heart of America's permit became current and active on April 26, 2016.

¹ All statutory references are to the Revised Statutes of Missouri 2016 as amended unless otherwise indicated.

5. Midwestern Holdings, LLC d/b/a Heartland Medical, LLC (“Heartland Medical”), 7955 Flint Street, Lenexa, Kansas, is permitted by the Board under permit number 2015008181. Heartland Medical’s permit was at all times relevant herein current and active.

6. Heartland Medical is a diabetic supply mail-order pharmacy which also dispenses other medications for its patients.

7. On or about September 7, 2016, the Board received email correspondence from pharmacist J.R. alleging that a pharmacy technician at Heart of America had been processing refills and receiving faxes for new orders for Heartland Medical without a pharmacist present.

8. Inspector Wolzak investigated the allegations and visited both Heartland Medical and Heart of America on September 21, 2016, as part of her investigation.

9. As of September 21, 2016, Heart of America had only two employees: pharmacy technician W.K. and Respondent.

10. Pharmacy technician W.K. became employed as a full-time pharmacy technician with Heartland Medical in November, 2015.

11. On April 5, 2016, pharmacy technician W.K. began working full-time at Heart of America.

12. Pharmacy technician W.K. told Inspector Wolzak that most of the time he was at Heart of America by himself with no pharmacist present.

13. Respondent officially started employment as the PIC of Heart of America on June 1, 2016, but was not physically present at Heart of America Pharmacy until August 1, 2016. Like pharmacy technician W.K., Respondent began his employment at Heartland Medical’s location.

14. Pharmacist J.R. started employment with Heartland Medical in February, 2016.

15. Pharmacist J.R. worked as the PIC of Heart of America until June 1, 2016, when she became a staff pharmacist at Heartland Medical.

16. On September 21, 2016, pharmacy technician W.K. explained to and showed Inspector Wolzak his daily employment duties at Heart of America while she observed.

17. Pharmacy technician W.K.'s work duties at Heart of America included processing prescription orders for Heartland Medical, including new prescriptions faxed to Heartland Medical and auto-order refills.

18. Pharmacy technician W.K. processed Heartland Medical's new prescription orders while working at Heart of America as follows:

A. He accessed Heartland Medical's database to select and review the orders and "adjudicate" them for submission to insurance, which means verifying the information on the order matched the prescription image generated on the computer.

B. Once submitted to insurance, he generated prescription labels on the computer and placed the labels in a network drive for employees at Heartland Medical to access, print and attach to the drug products it mailed out to patients.

19. Pharmacy technician W.K.'s work duties at Heart of America also included accessing Heartland Medical's database to determine whether Heartland Medical's patients were due for refills, the process for which was as follows:

A. He accessed Heartland Medical's "pending order queue" which contained prescriptions due for 90-day auto-order refills.

B. He then reviewed comments left by Heartland Medical's customer services representative who had previously contacted the patient to determine whether the refill was needed.

C. If the patient said no refill was necessary, W.K. would change the refill date to 30 days later or a date specifically indicated by the patient.

D. If a refill was necessary, W.K. processed the refill as described above for new prescription orders.

20. Pharmacy technician W.K. also was part of a group e-mail alert system involving Heartland Medical patients who needed supplies before their prescription was due for the 90-day auto-order refill or for some other circumstance needing quick review. W.K. reviewed and made the decision on outcomes for these email alerts at Heart of America daily until 12:00 pm.

21. Pharmacy technician W.K. also handled returns for Heartland Medical based on wrong patient addresses or refusal of delivery while working at Heart of America, as follows:

A. He accessed the “returns queue” in the Heartland Medical database and called the patient to see if there was an updated address.

B. If the patient did not answer, he updated the system, reversed the order and put the order on hold.

C. If the patient gave a new address, the product would be re-shipped to new address.

D. If the patient refused, he reversed the order and put it on hold until the patient was ready to receive more product.

22. Pharmacy technician W.K. estimated that he assisted Heartland Medical with 50 prescriptions per day while working at Heart of America.

23. On September 21, 2016, while working at Heart of America, pharmacy technician W.K. initiated the filling process for 29 prescriptions to be labeled and shipped from Heartland Medical for 11 patients.

24. Pharmacist J.R. verifies approximately 150 prescriptions per day at Heartland Medical, half of which are processed at Heart of America.

25. Records show that between April 5, 2016, and April 25, 2016, while Heart of America was an unlicensed pharmacy, pharmacy technician W.K. submitted and initiated the filling of prescriptions for Heartland Medical while working at Heart of America.

26. Records show that between June 1, 2016, and July 31, 2016, pharmacy technician W.K. submitted and initiated the filling of prescriptions for Heartland Medical while working at Heart of America without a pharmacist physically present and supervising.

27. While visiting Heartland Medical on September 21, 2016, Inspector Wolzak was told by General Manager/Pharmacy Manager/Pharmacy Technician F.L. that Heart of America was “locking down” for the day. F.L. explained “locking down” meant closing down.

28. General Manager/Pharmacy Manager/Pharmacy Technician F.L. also told Inspector Wolzak that “moving forward,” pharmacy technician W.K. would be working only at Heartland Medical until insurance contracts and claims were ready at Heart of America.

29. Neither Heart of America nor Heartland Medical have a Class J permit.

30. On March 22, 2017, the Board made demand on Heart of America to cease and desist Class-J Shared Service activities with Heartland Medical in the State of Missouri without a Class-J pharmacy permit.

31. By correspondence dated April 4, 2017, Heart of America advised the Board that it had “terminated the processes” described in the Board’s March 22, 2017 cease and desist letter.

32. Missouri law states:

(6) A pharmacy permit shall be required for performing non-dispensing activities if the pharmacist is using a pharmacy technician to assist in the practice of pharmacy at the location where non-dispensing activities are being performed, provided that a pharmacy permit shall not be required for sites used solely by the pharmacist for administering vaccines as authorized by Chapter 338, RSMo, and the rules of the board. Pharmacy technicians shall only be authorized to work under the direct supervision of a pharmacist as provided by section 338.013, RSMo, and 20 CSR 2220-2.700.

20 CSR § 2220-6.055(6).

33. Missouri statute defines “pharmacy” as:

1. Pharmacy refers to any location where the practice of pharmacy occurs or such activities are offered or provided by a pharmacist or another acting under the supervision and authority of a pharmacist, including every premises or other place:

- (1) Where the practice of pharmacy is offered or conducted;
- (2) Where drugs, chemicals, medicines, any legend drugs under 21 U.S.C. Section 353, prescriptions, or poisons are compounded, prepared, dispensed or sold or offered for sale at retail;
- (3) Where the words “**pharmacist**”, “**apothecary**”, “**drugstore**”, “**drugs**”, and any other symbols, words or phrases of similar meaning or understanding are used in any form to advertise retail products or services;
- (4) Where patient records or other information is maintained for the purpose of engaging or offering to engage in the practice of pharmacy or to comply with any relevant laws regulating the acquisition, possession, handling, transfer, sale or destruction of drugs, chemicals, medicines, prescriptions or poisons.

§ 338.210.1, RSMo.

34. Missouri law defines the practice of pharmacy as:

1. The “**practice of pharmacy**” means the interpretation, implementation, and evaluation of medical prescription orders, including any legend drugs under 21 U.S.C. Section 353; receipt, transmission, or handling of such orders or facilitating the dispensing of such orders; the designing, initiating, implementing, and monitoring of a medication therapeutic plan as defined by the prescription order so long as the prescription order is specific to each patient for care by a pharmacist; the compounding, dispensing, labeling, and administration of drugs and devices pursuant to medical prescription orders and administration of viral influenza, pneumonia, shingles, hepatitis A, hepatitis B, diphtheria, tetanus,

pertussis, and meningitis vaccines by written protocol authorized by a physician for persons twelve years of age or older as authorized by rule or the administration of pneumonia, shingles, hepatitis A, hepatitis B, diphtheria, tetanus, pertussis, and meningitis vaccines by written protocol authorized by a physician for a specific patient as authorized by rule; the participation in drug selection according to state law and participation in drug utilization reviews; the proper and safe storage of drugs and devices and the maintenance of proper records thereof; consultation with patients and other health care practitioners, and veterinarians and their clients about legend drugs, about the safe and effective use of drugs and devices; and the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management and control of a pharmacy. No person shall engage in the practice of pharmacy unless he is licensed under the provisions of this chapter. This chapter shall not be construed to prohibit the use of auxiliary personnel under the direct supervision of a pharmacist from assisting the pharmacist in any of his or her duties.

§ 338.010.1, RSMo.

35. The Pharmacy violated 20 CSR § 2220-6.055(6), § 338.010.1, RSMo, and § 338.210.1, RSMo by authorizing a pharmacy technician to assist in the filling, entering, reviewing, processing, adjudicating, and/or verifying of prescriptions and orders at the Pharmacy's location prior to obtaining a Missouri pharmacy permit.

36. Missouri law also states:

(1) In lieu of a non-electronic (manual) record-keeping system, a pharmacy may elect to maintain an electronic data processing (EDP) record keeping-system. All information concerning the compounding, dispensing, or selling by a pharmacy of any drug, device, or poison pursuant to a lawful prescription which is entered into an EDP system at any pharmacy shall be entered only by a licensed pharmacist or by a technician or intern pharmacist under the direct supervision and review of a licensed pharmacist. Prior to dispensing, a pharmacist shall personally verify the accuracy of prescription data entered into the EDP for each original prescription. The EDP system shall comply with all applicable state and federal controlled substance laws and regulations.

20 CSR § 2220-2.080(1).

37. Missouri law further provides:

(1) A pharmacy technician is defined as any person who assumes a supportive role under the direct supervision and responsibility of a pharmacist and who is

utilized according to written standards of the employer or the pharmacist-in-charge to perform routine functions that do not require the use of professional judgement in connection with the receiving, preparing, compounding, distribution, or dispensing of medications.

20 CSR § 2220-2.700(1).

38. By allowing a pharmacy technician at the Pharmacy's location who was not under the direct supervision of a pharmacist to assist in the filling, entering, reviewing, processing, adjudicating, and/or verifying of prescriptions and orders to be dispensed by Heartland Medical, the Pharmacy violated 20 CSR § 2220-6.055(6), 20 CSR § 2220-2.080(1) and 20 CSR § 2220-2.700(1).

39. A Class J Shared Service pharmacy permit is defined in 20 CSR § 2220-2.020(9) as follows:

(J) Class J: Shared Service. A pharmacy engaged in the processing of a request from another pharmacy to fill or refill a prescription drug order, or that performs or assists in the performance of functions associated with the dispensing process, drug utilization review (DUR), claims adjudication, refill authorizations, and therapeutic interventions;

40. Missouri law defines the circumstances under which a pharmacy may share services with another pharmacy, which include each pharmacy location obtaining a Class J permit, to-wit:

(1) Class J: Shared Services: Shared Service Pharmacy is defined as the processing by a pharmacy of a request from another pharmacy to fill or refill a prescription drug order, or that performs or assists in the performance of functions associated with the dispensing process, drug utilization review (DUR), claims adjudication, refill authorizations, and therapeutic interventions.

(A) A pharmacy may perform or outsource centralized prescription processing services provided the parties:

1. Have the same owner, or have a written contract outlining the services to be provided and the responsibilities and accountabilities of each party in

fulfilling the terms of said contract in compliance with federal and state laws and regulations;

2. Maintain separate licenses for each location involved in providing shared services; and

3. Share a common electronic file to allow access to sufficient information necessary or required to fill or refill a prescription drug order. 20 CSR § 2220-2.650(1)(A).

41. The Pharmacy violated 20 CSR § 2220-2.650(1)(A) by failing to obtain a Class J permit and by sharing services with another pharmacy that also did not have a Class J permit.

42. By operating as a Class J pharmacy without a valid Class J pharmacy permit, the Pharmacy also violated 20 CSR § 2220-2.020(10), which states:

(10) Pharmacy applications for initial licensure or renewals of a license shall accurately note each class of pharmacy that is practiced at the location noted on the application or renewal thereof. The permit (license) issued by the board shall list each class of licensure that the pharmacy is approved to engage in. Whenever a change in service classification occurs at a pharmacy the permit must be sent to the board with a notarized statement explaining any additions or deletions of pharmacy classes that are to be made.

43. By operating as a Class J pharmacy without a valid Class J pharmacy permit, the Pharmacy also violated § 338.220.1(10), RSMo, which prohibits the opening, establishment, operation, or maintenance of a pharmacy without first obtaining a proper permit from the Board, to-wit:

1. It shall be unlawful for any person, copartnership, association, corporation or any other business entity to open, establish, operate, or maintain any pharmacy as defined by statute without first obtaining a permit or license to do so from the Missouri board of pharmacy. The following classes of pharmacy permits or licenses are hereby established:

* * *

(10) Class J: Shared service.

PIC Violations

44. All of the above referenced violations committed by Respondent, the Pharmacy and its staff may be imputed to Respondent, who is ultimately charged with responsibility to ensure that the Pharmacy is operated in full compliance of all state and federal laws and regulations concerning the practice of pharmacy.

45. Further, the above referenced violations committed by Respondent, the Pharmacy and its staff may be imputed to Respondent, who is ultimately charged with responsibility to ensure that the Pharmacy policies and procedures are in force to ensure safety for the public concerning any action by pharmacy staff members or any action within the pharmacy physical plant.

46. As PIC, Respondent also is charged with responsibility to ensure that the Pharmacy is operated in full compliance of all state and federal laws and regulations concerning the practice of pharmacy pursuant to § 338.210.5, RSMo, which states:

5. If a violation of this chapter or other relevant law occurs in connection with or adjunct to the preparation or dispensing of a prescription or drug order, any permit holder or pharmacist-in-charge at any facility participating in the preparation, dispensing, or distribution of a prescription or drug order may be deemed liable for such violation.

47. As pharmacist-in-charge, Respondent's failure to supervise pharmacy personnel to assure full compliance with state and federal pharmacy laws and regulations, and Respondent's failure to implement and enforce policies and procedures to effectively insure the public safety is in violation of 20 CSR 2220-2.090(2)(A), (N)-(P), (W) and (CC) which states, in pertinent part:

(2) The responsibilities of a pharmacist-in-charge, at a minimum, will include:

* * *

(A) The management of the pharmacy must be under the supervision of a Missouri-licensed pharmacist at all times when prescriptions are being compounded, dispensed or sold;

* * *

(N) The pharmacist-in-charge will be responsible for the supervision of all pharmacy personnel, to assure full compliance with the pharmacy laws of Missouri;

(O) All Missouri and federal licenses are kept up-to-date;

(P) Policies and procedures are in force to insure safety for the public concerning any action by pharmacy staff members or within the pharmacy physical plant;

* * *

(W) Assure full compliance with all state and federal drug laws and rules.

* * *

(CC) Maintain written standards setting out the responsibilities of registered pharmacy technicians as well as the procedures and policies for supervision of registered pharmacy technicians, as required by 4 CSR 220-2.700(1). Said standards shall be available to the board and its designated personnel for inspection and/or approvals;

JOINT CONCLUSIONS OF LAW

48. Respondent's conduct is cause for disciplinary action against his license to practice pharmacy under § 338.055.2(5), (6), (13) and (15), RSMo, which provides:

2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit or license for any one or any combination of the following causes:

* * *

(5) Incompetence, misconduct, gross negligence, fraud, misrepresentation or dishonesty in the performance of the functions or duties of any profession licensed or regulated by this chapter;

(6) Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;

* * *

(13) Violation of any professional trust or confidence.

* * *

(15) Violation of the drug laws or rules and regulations of this state, any other state or the federal government;

JOINT AGREED DISCIPLINARY ORDER

Based upon the foregoing, the parties mutually agree and stipulate that the following shall constitute the disciplinary order entered by the Board in this matter under the authority of Section 621.045.3, RSMo:

A. Respondent's license, License No. 044202, is hereby **PUBLICLY CENSURED**.

B. The terms of this Settlement Agreement are contractual, legally enforceable, binding, and not merely recitals. Except as otherwise contained herein, neither this Settlement Agreement nor any of its provisions may be changed, waived, discharged, or terminated, except by an instrument in writing signed by the party against whom the enforcement of the change, waiver, discharge, or termination is sought.

C. Respondent, together with his heirs and assigns, and his attorneys, does hereby waive and release the Board, its members and any of its employees, agents, or attorneys, including any former board members, employees, agents, and attorneys, of, or from, any liability,

claim, actions, causes of action, fees, costs and expenses, and compensation, including, but not limited to any claims for attorney's fees and expenses, including any claims pursuant to Section 536.087, RSMo, or any claim arising under 42 U.S.C. Section 1983, which may be based upon, arise out of, or relate to any of the matters raised in this litigation, or from the negotiation or execution of this Settlement Agreement. The parties acknowledge that this paragraph is severable from the remaining portions of this Settlement Agreement in that it survives in perpetuity even in the event that any court of law deems this Settlement Agreement or any portion thereof void or unenforceable.

RESPONDENT, AS EVIDENCED BY THE INITIALS ON THE APPROPRIATE LINE,

_____ **REQUESTS**

_____ *AK* **DOES NOT REQUEST**

THE ADMINISTRATIVE HEARING COMMISSION TO DETERMINE IF THE FACTS SET FORTH HEREIN ARE GROUNDS FOR DISCIPLINING RESPONDENT'S LICENSE TO PRACTICE PHARMACY.

The parties to this Agreement understand that the Board of Pharmacy will maintain this Agreement as an open record of the Board as provided in Chapters 324, 338, 610, RSMo.

If Respondent has requested review, Respondent and Board jointly request that the Administrative Hearing Commission determine whether the facts set forth herein are grounds for disciplining Respondent's license and issue findings of fact and conclusions of law stating that the facts agreed to by the parties are grounds for disciplining Respondent's license. Effective fifteen (15) days from the date the Administrative Hearing Commission determines that the

Settlement Agreement sets forth cause for disciplining Respondent's license, the agreed upon discipline set forth herein shall go into effect.

If Respondent has not requested review by the Administrative Hearing Commission, the Settlement Agreement goes into effect fifteen (15) days after the document is signed by the Board's Executive Director.

RESPONDENT

DOUGLAS C. KLEIN




Douglas C. Klein

Date: 8 August 2018

PETITIONER

MISSOURI BOARD OF
PHARMACY

By:

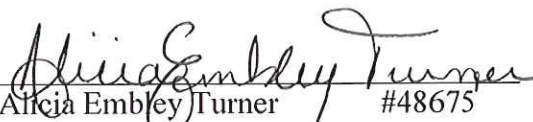


Kimberly Grinston
Executive Director

Date: 8-23-18

NEWMAN, COMLEY & RUTH P.C.

By:



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